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EXAMINER	
HOLLOWAY, IAN KNOBEL	
ART UNIT	PAPER NUMBER
4148	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,394	NEFTEL, FREDERIC	
	Examiner	Art Unit	
	Ian K. Holloway	4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/15/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *(06/07/2005),(5/23/2005),(7/15/2004)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "**18**" and "**22**" have both been used to designate t**he means for communication**. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "**9**" and "**23**" have both been used to designate **the valve**. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of

any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters **"19"** and **"21"** have both been used to designate **a valve**. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **(17)**. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The phrase "**connected to the patient peritoneum**" must be rephrased so that the device is "**adapted to be connected**".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-6, 8-9, 12, 14, 17-23 are rejected under 35 U.S.C. 102(e) as being anticipated by **Dadson (US Patent 6228047)**.

Regarding **Claim 1**, **Dadson** discloses: Automatic peritoneal dialysis sampling system adapted to automatically sample at specific time intervals (Column 6, lines 7-8) volumic fractions of a dialysate contained in the peritoneum of a patient in order to evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient, said peritoneal dialysis sampling system being characterized by the fact that it comprises a series of sampling containers (15) , pumping means (Column 3, lines 53-58) and a series of valves (Fig 3., Column 6, lines 6-21) adapted to direct a certain quantity of each fluid sample to a specific sampling container. (15)

Regarding **Claim 2, Dadson** discloses: a supplying line (12) and supplying means (P1) for supplying dialysis fluid to a peritoneal cavity, a draining line (15), draining means (P1) for draining the fluid from said peritoneal cavity, connecting means for allowing a connection to a Y-site (Fig. 1, a mixing chamber can be seen, which acts similar to the Y-site) on the draining line which is situated between the patient peritoneum (10a) and the draining means (15) of the peritoneal dialysis system.

Regarding **Claim 3**, **Dadson** discloses: means for defining the specific time intervals for sampling volumic fractions in relation with the peritoneal dialysis program sequences. (Microprocessor, 19, Column, lines 7-8)

Regarding **Claim 4**, **Dadson** discloses: means for allowing the use of different peritoneal dialysis liquids and/or different concentrations for each exchange cycle. (Column 7, lines 9-10)

Regarding **Claim 5**, **Dadson** discloses: means for allowing the automatic sampling during the dwell time of the peritoneal dialysis cycle and/or during the drain cycle. (19)

Regarding **Claim 6**, **Dadson** discloses: valves are of electromagnetic type. (Column 6, line 13)

Regarding **Claim 8**, **Dadson** discloses: connecting means for connecting it to the draining line between the draining means and a waste collector In order to collect samples of specific drain cycles. (15)

Regarding **Claim 9**, **Dadson** discloses: means for eliminating a volume of liquid between two samplings at feast equivalent to the dead volume contained between the patient and the sampling level. (Column 8, lines 37-51)

Regarding **Claim 12**, **Dadson** discloses: a memory key which contains all the necessary data to program the functioning of said automatic peritoneal dialysis sampling system and to store the sampling information. (19)

Regarding **Claim 14**, **Dadson** discloses: sampling containers contain vacuum in order to draw the liquid automatically when in open connection with the drawing line. (17)

Regarding **Claim 17**, **Dadson** discloses: analyzing means for directly analyzing of at least one characteristic of the sample in-line, such as by spectroscopy, fluorometry or by use of chemical or electro-chemical means. (Column 10, lines 24-30)

Regarding **Claim 18**, **Dadson** discloses: analyzing means allows the measurement of at least one of the following constituents or characteristics: glucose, urea, creatinine, Sodium, Chloride, albumine, proteins, osmolarity or ph. (Column 10, 30-41)

Regarding **Claim 19**, **Dadson** discloses: means (19) which use the result of the in-line analysis to optimize the next peritoneal dialysis exchange cycle or sampling intervals in order to improve the membrane characteristics evaluation and/or improve the peritoneal dialysis for a specific patient. (Column 3, lines 34-40)

Regarding **Claim 20**, **Dadson** discloses: means for defining the specific time intervals for sampling volumic fractions in relation with the peritoneal dialysis program sequences. (19)

Regarding **Claim 21**, **Dadson** discloses: means for using different peritoneal dialysis liquids and/or different concentrations for each exchange cycle, whether it is a tidal exchange or a full exchange cycle. (S1, S2, G1, G2, M)

Regarding **Claim 22**, **Dadson** discloses: means for allowing the automatic sampling to occur during the dwell time of the peritoneal dialysis cycle and/or during the

drain cycle in order to improve the evaluation of the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a specific patient. (19)

Regarding **Claim 23**, **Dadson** discloses: means for eliminating a volume of liquid at least equivalent to the dead volume contained between the patient and the sampling level between two samplings. (15)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Dadson** in view of **Klein et al. (US Patent 4244787)**.

Regarding **Claim 7**, **Dadson** fails to disclose a peristaltic pumping means.

However, **Klein et al.** teaches the use of a peristaltic pump in conjunction with an APD device. (19)

Dadson discloses the claimed invention except for the pump type. **Klein et al.** teaches that it is known to use a peristaltic pump. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to replace the syringe pump with a peristaltic one as taught by **Klein et al.,** since such modification would make the device more reliable.

Thus, it would have been obvious to one having ordinary skill in the art to modify the pumping means taught by **Dadson** in view of the peristaltic pump shown by **Klein et al.**, since the pumping means is in no way dependent on the type of pump used. A peristaltic pump could be used in combination with the device of **Dadson** to achieve the predictable result of providing a pumping means.

Regarding **Claim 10**, **Dadson** fails to disclose the two piece exchange system.

However, **Klein et al.** teaches a larger analysis device to be used instead of the simpler analysis system of **Dadson.** The exchange system is shown as hooked in line with the waste line, and since the analysis system of **Dadson** communicated with the microprocessor, it can be assumed that the combination of these devices would do the same.

Regarding **Claim 11**, **Dadson** discloses the fact that data is exchanged between its analysis system and its dialysis system. (Improvements are made from analysis of waste fluid)

12. Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Dadson** in view of **Suzuki et al. (US Patent 6595948)**.

Regarding **Claim 13**, **Dadson** fails to disclose the use of soft pouches.

However **Suzuki et al.** teaches the use of soft pouches. (4-6)

Dadson discloses the claimed invention except for the use of soft pouches. **Suzuki et al.** teaches that it is known to use soft pouches to hold fluid in peritoneal dialysis. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the soft pouches as taught by **Suzuki et al.,** since such modification would make the device more effective.

Thus, it would have been obvious to one having ordinary skill in the art to modify the pouches taught by **Dadson** in view of the soft pouches shown by **Suzuki et al.**, since the operation of the device is in no way dependent on how the fluid is carried. Soft pouches could be used in combination with the device of **Dadson** to achieve the predictable result of providing fluid for peritoneal dialysis.

Regarding **Claim 16**, **Dadson** fails to disclose a cooling circuit.

However **Suzuki et al.** teaches the use of a cooling circuit for dialysis fluid. (Column 7, line 16)

13. Claims 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Dadson** in view of **Skeggs (US Patent 2797149)**.

Regarding **Claim 15 and 24**, **Dadson** fails to disclose the use of separating samples with air bubbles.

However, **Skeggs** teaches the process of separating samples with air bubbles. (Claim 1)

Dadson discloses the claimed invention except for the air bubbles. **Skeggs** teaches that it is known to separate samples with air bubbles in a process called

Segmented Flow analysis. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to try segmented flow analysis as taught by **Skeggs,** since such modification would make the device more effective.

Thus, it would have been obvious to one having ordinary skill in the art to modify the sampling procedure taught by **Dadson** in view of the Segmented Flow Analysis shown by **Skeggs**, since how the samples are analyzed is in no way dependent on how they are separated. Segmented Flow Analysis could be used in combination with **Dadson's** device to achieve the predictable result of providing samples for analysis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN K. HOLLOWAY whose telephone number is (571)270-3862. The examiner can normally be reached on 8-5, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell L. McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian K. Holloway
1-4-08

/Terrell L Mckinnon/
Supervisory Patent Examiner, Art Unit 4148